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*The Validity and Value of Label
Comprehension Studies in
Establishing Consumer
Understanding*

S. J. Hellebusch, Ph.D.

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Thank you for this opportunity to speak. By way of introduction, I am Steve Hellebusch, President of Q2 Marketing Research, Inc. I have a Ph.D. in Experimental Psychology, and 20+ years of experience in consumer research. I am not being compensated to be here.

I am here because I am very interested in the topic of Rx-to-OTC Switch, and in the use of consumer behavioral research to help answer some of the questions surrounding Switches. I have conducted label comprehension studies since 1989, and have seen the procedure evolve. I was somewhat surprised by the tonality of the questions FDA asked concerning consumer understanding, which struck me as challenging the usefulness of consumer research, and I would like to provide some assurances.

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Label Comprehension Testing

- A valid method of psychological testing.
- An iterative, case-specific process.
- A useful tool to ensure consumer understanding and allow for data-driven decisions.

I would like to make three points concerning Label Comprehension Testing specifically. It is a valid method of psychological testing. Many of us would not be here if psychological testing, in the form of the GREs or some other standardized test had not assured an educational institution of our comprehension level.

Label Comprehension testing is iterative. Typically, more than one study is conducted to make certain the label is the best it can be.

Label Comprehension testing, and, indeed, consumer research, is a useful tool for making Switch decisions based on data. Sound scientific decisions are driven by facts.

Label Comprehension Testing = Psychological Testing

Validity: “the degree to which the test actually measures what it purports to measure.”

- Content
- Construct
- Criterion-related

Validity, in psychological testing, is defined as “the degree to which the test actually measures what it purports to measure.” There are three specific categories of validity.

Content validity refers to the nature of the subject. In the case of Label Comprehension testing, it is the communication objectives for the label.

Construct validity refers to “comprehension” the psychological construct being measured. I think of it as making certain the test is constructed in an unbiased fashion to achieve this measurement.

Criterion-related validity determines whether the test measurement is related to an independent measure of whatever the test is designed to measure. In Label Comprehension testing, it is useful to have a control or comparator, to relate the results to the real world.

An Example

Objective: determine whether users of a certain prescription drug understood they were not to use a Switch candidate without consulting with doctor.

- Content Validity: address a single communication objective in this subgroup of the population.
- Construct Validity: Ask fairly. Open-ended.

An example is a Label Comprehension test designed with the objective of determining whether users of a certain prescription drug understood that they were not to use the switch product without consulting a doctor.

Content validity is demonstrated in the fact that a clear communication objective was established.

Construct validity was demonstrated in this case by asking unbiased, open-ended questions to determine target consumers' comprehension of this point.

Criterion-related Validity

- Found an existing OTC label which included the same warning.
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- Results showed that the target population had a high intent to heed, as high as that for the same warning on the existing OTC.

Criterion-related validity is established by testing the same warning, as found on an existing OTC product.

The results of this test showed that the target population had a high intent to heed the warning that was tested, in both the Switch candidate's labeling and in the existing product's labeling. There was no difference between the two. It was known that the existing product did not have difficulties with the issue, giving confidence that the Switch candidate would not experience difficulties. This Switch candidate is now an approved OTC, and has experienced no problems. The consumer label comprehension study provided valuable data for this OTC decision.

Label development is an iterative process.

Every switch is unique. So is the label testing.

- Rogaine Extra Strength for Men
- Nicorette and Nicoderm

I was involved in the Nicorette and Nicoderm switches, as well as the approval of Rogaine 5%, better known as Rogaine Extra Strength for Men.

For the Smoking Cessation products, we conducted eight different label comprehension tests. For Rogaine Extra Strength for Men, we conducted five. As we learned more, we tried other ways to communicate to find the best way.

This process has evolved and improved over time. Today, for example, if a manufacturer approaches us with a label developed internally, we recommend beginning with qualitative research, to identify and fix any glaring misunderstandings before large-sample label comprehension testing occurs. The iterative process of OTC label development is a key aspect that makes these studies essential to Switch.

Label Comprehension Testing is a useful tool.

But don't expect a perfect score.

A small example:

- 545 consumers were asked exact age at start and end of a 15 minute telephone interview.
- 6% changed age. 4% stayed within a year. 2% varied widely.

Label Comprehension testing has shown itself to be a useful and valid tool in all three of the cases I have referred to, helping the manufacturer and FDA make sound decisions based on data.

But expectations need to be set appropriately. There will always be a small percentage of consumers who are either so uninvolved with the research that they are inattentive, or are not taking it seriously.

Six percent changed their ages in my small example. My interpretation is that the 4% who stayed within a year were just a little confused, but the 2% who changed age by more than one year are an indicator of the percent who are not taking the testing seriously.

These types of data fit well with the points Dr. Soller made yesterday, that Switch candidates need not have an "expectation that 100% of the target population will have 100% benefit". The judgment is to be made in relative terms.

Summary

- Label Comprehension Testing is a valid psychological testing procedure.
- It has developed into an iterative process, case-specific.
- It is a very useful tool to ensure consumer understanding, and help all involved make data driven decisions.

In summation, Label Comprehension Testing is a form of psychological testing that is a valid scientific tool. It has evolved into an iterative procedure that improves labeling in development, and it has become essential to the Switch process.

As I mentioned, I am a researcher. I am not a regulatory affairs professional. But I always thought that everyone involved in Switches was trying to do the best thing for the public health. Why wouldn't all involved welcome any discipline that would provide another means of learning about the public? Label Comprehension testing, and consumer research in general, has been and can be very useful in helping make sound judgments in Switch situations.